UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/824,983	04/15/2004	G. Ian Rowlandson	146462IT (5024-00124)	7541

26753 7590 10/29/2007

ANDRUS, SCEALES, STARKE & SAWALL, LLP
100 EAST WISCONSIN AVENUE, SUITE 1100
MILWAUKEE, WI 53202

EXAMINER	
REIDEL, JESSICA L	

ART UNIT	PAPER NUMBER
3766	

MAIL DATE	DELIVERY MODE
10/29/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/824,983	ROWLANDSON ET AL.	
	Examiner	Art Unit	
	Jessica L. Reidel	3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 August 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,6,8,10,12-20,41 and 42* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,6,8,10,12-20,41 and 42* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *07 December 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Acknowledgment is made of Applicant's Amendment, which was received by the Office On August 16, 2007. Claims 5, 7, 9, 11 and 21-40 have been cancelled. Claims 1-4, 6, 8, 10, 12-20, 41 and 42 are pending.

Specification

2. In view of the response filed August 16, 2007, the objection made against the Specification in the Office Action of May 21, 2007 has been withdrawn. The Examiner accepts the amended title.

Claim Objections

3. In view of the response filed August 16, 2007, the objections made against the claims in the Office Action of May 21, 2007 have been withdrawn.

Claim Rejections - 35 USC § 112

4. In view of the response filed August 16, 2007, the 35 U.S.C. 112, second paragraph rejections applied against the claims in the Office Action of May 21, 2007 have been withdrawn.

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. ***Claims 1-4, 6, 8, 10 and 12-20 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement.*** The claim(s) contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant

art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The Examiner finds support at page 8, paragraph 28 of Applicant's disclosure for the sudden cardiac death (SCD) risk assessment tool 30 displayed as an icon on any patient monitor 16 such that a healthcare provider may access the tool 30 by clicking on the icon representing the SCD risk assessment tool 30 in order to run the SCD assessment tool 30. The Examiner is unable to find, however, support throughout Applicant's disclosure for a SCD risk assessment tool that is accessible via "an executable switch" on any one of a plurality of patient monitors where such a "switch" is different than the clickable "icon" previously discussed. It is to the Examiner's best understanding that "an executable switch" on any one of a plurality of patient monitors that is not the clickable icon is not discussed or defined anywhere throughout Applicant's originally filed disclosure.

Claim Rejections - 35 USC § 101

7. In view of the response filed August 16, 2007, the 35 U.S.C. 101 rejections applied against the claims in the Office Action of May 21, 2007 have been withdrawn.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the Examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the

contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the Examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. ***Claims 41 and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Erkkila in view of Bayer.*** As to Claims 41 and 42, Erkkila expressly discloses a method of assessing a risk of sudden cardiac death for a patient (see Erkkila Abstract) comprising identifying a patient as being worthy of an on-going sudden cardiac death risk assessment when the patient arrives at a hospital (steps 301 and 302) and performing the on-going sudden cardiac death assessment whenever new patient data (i.e. new measured signal parameters) is/are acquired at a sever 605 (see Erkkila pages 4-5, paragraphs 59-60). Server 605 of Erkkila exists as one of a plurality of healthcare locations, which includes a patient monitor 607. Bedside apparatus exists as another one of a plurality of healthcare locations, which also includes a patient monitor 604 (see Erkkila Fig. 6). Erkkila specifies that a probability of sudden cardiac death for the patient is calculated as a sudden cardiac death risk index (SCDRI) and further that the SCDRI is based on the new patient data, specifically the newly measured signal parameters received at server 605 from the bedside monitoring apparatus (see Erkkila page 1, paragraph 2, page 2, paragraphs 14-29 and page 5, paragraph 60). The method of Erkkila includes comparing the SCDRI to a reference or threshold value set at step 303 where the reference or threshold value depends on an initial calculation of SCDRI (i.e. it is specific to the patient). The Examiner considers the reference or threshold value of Erkkila synonymous with the at least one probability constant specific for the patient of Applicant. Erkkila expressly discloses that a healthcare provider is alerted if the probability of sudden cardiac death, i.e. the SCDRI is greater than the reference or threshold which is a probability constant specific to the patient (see Erkkila page 3,

paragraphs 42-45 and pages 4-5, paragraphs 60-65). Additionally, Erkilla expressly discloses that the SCDRI is displayed on a patient monitor 604 located at one of a plurality of healthcare locations (see Erkilla Fig. 6 and page 5, paragraph 59).

Erkkila expressly discloses the claimed invention as discussed above except that it is not specified that the identification of the patient being worthy of an on-going sudden cardiac death risk assessment be based on acquired patient data where the patient data is acquired at one of a plurality of healthcare locations. It is inherent, or at least obvious to one having ordinary skill in the art at the time the invention was made that a nurse or physician would "acquire data from the patient" upon the patient's arrival at the hospital (i.e. while the patient is in the emergency room) in order to determine whether or not it is necessary to perform the sudden cardiac death risk assessment as previously discussed, otherwise the method of Erkkila would be performed on a plurality of patients where determining an SCDRI is unnecessary. Specifically, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method of Erkkila with the steps of acquiring the patient's symptoms which brought the patient to the hospital and subsequently identifying that patient as being worthy of the on-going sudden cardiac death risk assessment based on that acquired data since it was known in the art that specific symptoms, such as a patient reporting chest pains, read as a pre-existing condition are used to reliably decide whether or not to assess a patient for the possible risk of heart attack. The Examiner provides Bayer as evidence of the conventionality of these steps (see Bayer page 3, paragraph 28).

11. ***Claims 1-4, 6, 8, 10, 12-15, 17-18 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Erkkila in view of Bayer and Krass.*** As to Claims 1-2, 10, 12, 15 and 17, Erkkila teach that a user interface 704 (display and control input) of the bedside monitor (see Erkkila Figs. 6-7) is provided which allows a nurse to operate the bedside monitor for performing the method of

assessing a risk of sudden cardiac death for a patient (see Erkkila page 5, paragraph 62). The previously modified Erkkila reference discloses the claimed invention except that it is not specified that a sudden cardiac death risk assessment tool be accessed via an executable switch on any one of the patient monitors 604, 607. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method as taught by Erkkila such that a user (i.e. the nursing staff) may press a start icon of a touch screen user interface of monitor 604 and/or monitor 607, since it was known in the art to provide a touch screen user interface for simplicity of control of a testing apparatus and to integrate a display and control input into one device. The Examiner provides Krass as evidence of the conventionality of this type of feature (see Krass column 4, lines 50-62). The Examiner considers a clickable start icon synonymous with an executable start switch, since upon clicking of the icon the test is switched on.

12. As to Claim 3, Erkkila discloses the claimed invention as discussed above except the reference is silent to the exact phrase "automatic". Erkkila does not specify that the on-going sudden cardiac death risk assessment be performed automatically. It would have been obvious to one having ordinary skill in the art at the time the invention was made to automatically perform the on-going sudden cardiac death risk assessment, since it has been held that broadly providing a mechanical or automatic means to replace manual activity, which has accomplished the same result, involves only routine skill in the art.

13. As to Claim 4, the method of Erkkila further includes acquiring both cardiological and non-cardiological patient data (see Erkkila page 4, paragraphs 50-58).

14. As to Claim 6, it is inherent that the method of Erkilla comprises acquiring patient data at an emergency room since it is specified that the method applies to monitoring a hospitalized patient in acute care (see Erkilla page 3, paragraph 39) and further since Erkilla specifies that the sudden

cardiac death risk assessment is started once the patient arrives at the hospital (see Erkilla Fig. 3 and page 3, paragraph 44). Erkilla also specifies that in alternative embodiments the invention may be used in care areas such as ambulatory care, nursing homes and in home care (see Erkilla page 5, paragraphs 64-65).

15. As to Claim 8, Erkilla discloses that acquired data may be stored in a database, read as hospital information system 606 and further that a server 605 accesses the acquired patient data from the hospital information system in order to perform the sudden cardiac death risk assessment (see Erkilla page 5, paragraph 60).

16. As to Claim 13, Erkilla expressly discloses that performing the on-going sudden cardiac-death risk assessment is based on an electrocardiogram (see Erkilla Figs. 1-4 and page 4, paragraph 54).

17. As to Claim 14, Erkilla expressly discloses that the method may further comprise performing the on going sudden cardiac death risk assessment based on measurements including blood pressure measurements (see Erkilla Figs. 1-3 and Fig. 5 and page 4, paragraphs 55-58).

18. As to Claim 18, Erkilla specifies that laboratory results may be manually selected as an input parameter upon which the on going sudden cardiac death risk assessment is performed (see Erkilla page 4, paragraph 58).

19. As to Claim 20, Erkilla expressly discloses that the method further comprises performing the on going sudden cardiac death risk assessment based upon cardiological patient data such as heart rate variability, an arrhythmia, rhythm abnormalities, repolarization phase analysis, late potentials and/or conduction abnormalties (see Erkilla Fig. 4, page 2, paragraphs 14-29 and page 4, paragraphs 50-54).

20. ***Claims 16 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Erkkila in view of Bayer and Krass as applied to claim 1 above, and further in view of Lozier et al. (U.S. 2004/0230456) (herein Lozier).*** Erkkila specifies that the method may be implemented as part of the local area network (LAN) of the hospital for transferring the signal parameters to a centralized server 605 (see Erkkila page 5, paragraph 60). The previously modified Erkkila reference discloses the claimed invention as discussed above except that it is not specified that the method include flagging an identification associated with a patient if the patient is worthy of an on-going sudden cardiac death risk assessment.

Lozier, however, teaches a software system for identifying patients who may be appropriate candidates for implementation with an implantable cardioverter/defibrillator (ICD) where the software system is implemented on a clinical data manager 102 of a hospital network 103. Lozier discloses comprises flagging (via color coding, a patient's name or secret coding) identification associated with the patient if the patient is worthy of an on-going sudden cardiac death risk assessment in order to identify one patient among a plurality of patients in a hospital network (see Lozier page 1, paragraph 9, page 2, paragraph 12 and page 3, paragraphs 18-19). Lozier discloses that a user may sort the patient records in a desired order based upon the values contained in particular data fields (such as sudden cardiac risk data field 205). The Examiner takes the position that when patient profiles/records are listed in hierarchical order such as this, each profile adjacent to each other in the list would at least partially match (see Lozier pages 2-3, paragraph 16-20). It would have been obvious to one having ordinary skill in the art to modify the network of the previously modified Erkkila reference to include the clinical data manager of Lozier such that patients who are at risk and may be eligible for ICD may be easily identified within the hospital information system.

Response to Arguments

21. Applicant's arguments filed August 16, 2007 have been fully considered but they are not persuasive. Applicant argues the Erkkila does not disclose acquisition of patient data from a plurality of healthcare locations, where each of the plurality of healthcare locations includes a patient monitor (see page 10, lines 3-10 of the Remarks). The Examiner respectfully disagrees and makes specific reference to Fig. 6 of the Erkkila reference. As previously discussed, server 605 of Erkkila exists as one of a plurality of healthcare locations, which includes a patient monitor 607. Bedside apparatus exists as another one of a plurality of healthcare locations, which also includes a patient monitor 604.

22. Applicant further argues that Erkkila "is not a distributed system that includes a plurality of healthcare locations that are configured to collect patient data for assessment purposes" (see page 10, lines 10-12 of the Remarks), however, the Examiner respectfully disagrees. As previously discussed, Erkkila expressly discloses that the bedside apparatus acquires physiological signals (i.e. data) from different sensors attached to the patient and that the server 605 acquires data from bedside apparatus and further acquires previous measurements (i.e. data) and reference data via database 606 for SCD risk assessment purposes (see Erkkila pages 4-5, paragraphs 59 and 60). Applicant has not provided sufficient evidence or convincing rationale that effectively distinguishes the distributed system of Erkkila, which comprises at least two healthcare locations that each acquire patient data for sudden cardiac death risk assessment, from that of Applicant's.

23. In response to Applicant's arguments against the references individually (see pages 10-11 of the Remarks), one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

24. In response to Applicant's arguments that the Applicant's "have deleted from independent claim 1 the limitation that the Examiner intended Krass to anticipate", the Examiner respectfully refers Applicant to the 35 U.S.C. 112, first paragraph rejections above in this Office Action. As previously discussed, the Examiner considers a clickable start icon synonymous with an executable start switch, since upon clicking of the icon the test is switched on. The Examiner finds no evidence, throughout the Remarks filed August 16, 2007 and throughout Applicant's originally filed disclosure distinguishing an executable switch from a clickable icon. Applicant has not provided sufficient evidence or convincing rationale that effectively distinguishes one from the other.

Conclusion

25. The prior art made of record and not relied upon is considered pertinent to Applicant's disclosure.

26. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

27. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Jessica L. Reidel whose telephone number is (571) 272-2129. The Examiner can normally be reached on Mon-Thurs 8:00-5:30, every other Fri 8:00-4:30.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Carl H. Layno can be reached on (571) 272-4949. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jessica L. Reidel/
Patent Examiner, Art Unit 3766
October 25, 2007

Carl H. Layno
CARL LAYNO
PRIMARY EXAMINER